Supreme Court, U.S.
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No. 92-160

In The

Supreme Court of the United States

October Term, 1992

RONNIE LEE and MACKEY LEE,
Individually and as Parents and Natural
Guardians of MICHAEL LEE, a Minor,

Petitioners,

v.

RICHARDSON-MERRELL, INC., n/k/a
MERRELL DOW PHARMACEUTICALS INC.,

Respondent.

Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Sixth Circuit

BRIEF FOR RESPONDENT MERRELL DOW PHARMACEUTICALS INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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Respondent, Merrell Dow Pharmaceuticals Inc., is a wholly-owned subsidiary of Marion Merrell Dow Inc., which is approximately two-thirds owned by The Dow Chemical Company. Their subsidiaries and affiliates which have securities in the hands of the public are the following:

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OTHER AUTHORITIES

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INTRODUCTION

Recently, in *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir. 1992) *petition for cert. filed*, No. 91-1987 (October Term, 1992), this Court was asked once again to determine the quantum of evidence required before a Bendectin plaintiff meets his burden of proof requiring submission of his case to a jury.[1] In this case, Petitioners echo the arguments raised by the *Turpin* petitioners.[2] In their Statement of the Case, Petitioners here include only eight new paragraphs beyond the arguments contained in the *Turpin* Petition.

Petitioners here, as well as in *Turpin*, ask this Court to revisit issues which have been previously deemed unworthy of this Court's review. This case presents neither a new issue nor one worthy of review, but only a fact specific application of established summary judgment standards and the determination that Petitioners' evidence, all of which had been presented to other courts and rejected, here also failed to raise a genuine issue of material fact. Contrary to Petitioners' assertions, this case involves neither an attempt to impose a nationwide uniformity on scientific issues to prevent inconsistent verdicts, nor an attempt by the judiciary to preclude

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[1] On four prior occasions, this Court has denied similar petitions. *See, Brock v. Merrell Dow Pharmaceuticals, Inc.*, 110 S.Ct. 1511 (1990); *Koller v. Richardson-Merrell, Inc.*, 111 S.Ct. 1391 (1991); *Richardson v. Richardson-Merrell, Inc.*, 110 S.Ct. 218 (1989); *Ealy v. Richardson-Merrell, Inc.*, 111 S.Ct. 370 (1990).

[2] Petitioners in both the *Turpin* and *Lee* cases are represented by the same Counsel of Record, Kenneth J. Chesebro, Esq.

resolution of future cases on the merits by judicial notice or by some form of a "pseudo-class action."

Petitioners ignore the distinction between admissibility of evidence and the sufficiency of that evidence to prove a particular fact. They do so in order to fabricate a conflict between the Federal Rules of Civil Procedure and Federal Rules of Evidence. However it may be burdened with words, Petitioners real point is quite simple. They argue that, where an expert's opinion is admissible, it is, perforce and as a matter of federal law, enough to prove the fact opined. Petitioners maintain that a federal court can *never* grant summary judgment against the opinion of any expert regardless of the weight of logic or evidence arrayed against such opinion, i.e., any admissible expert opinion precludes summary judgment. Petitioners' formulation of the "Questions Presented" by their petition avoids the real legal question of the case.

To secure reversal of the district court's ruling that they failed to present evidence sufficient to warrant a jury trial, Petitioners now ask this Court to define sufficiency to fit their evidence. However, the only rule of general utility to the federal courts which this Court could formulate to oblige the Petitioners would be that any admissible expert opinion will *always* defeat a motion for summary judgment on the fact opined. Such a standard for summary judgment is not – and should not become – the law. No other type of evidence is recognized by law as being categorically of the type believable by a reasonable juror.

This case presents no conflict among the circuits. It presents only a failure of a particular plaintiff to produce

evidence sufficient to overcome a well pled motion for summary judgment. For these reasons, and those set forth below, the instant petition and that pending in *Turpin* should be denied.

COUNTER-STATEMENT OF THE CASE

Petitioners' Statement of the Case goes beyond the district court's express analysis of the record, attempting to divine the district court's interpretation of affidavits submitted by Respondents in opposing the motion for summary judgment. These impressions are not found anywhere within the record before this Court. Accordingly, Respondent will, in this counterstatement, describe the lower court's analysis of the record in this case as well as the documented record concerning Bendectin.

Additionally, pursuant to Rule 15.1 of the Rules of the Supreme Court of the United States, Respondent addresses the following misstatements of fact set forth in the Petition. On page 2 of the Petition, Petitioners state that "[n]o identifiable risk factor other than the ingestion of Bendectin was present." While it is true that Petitioners *alleged* this fact, the affidavit of Sherman Elias, M.D., provided:

> . . . I have concluded that limb defects of the type found in Michael Lee could be genetic in origin either as a dominant trait expressed in the other members of the same family or as a new mutation expressed for the first time.

See, Affidavit dated June 25, 1990, of Sherman Elias, M.D., at ¶8.

At page seven of the Petition, Petitioners state that "the court of appeals stated that there was no need to engage in a *de novo* analysis of the record in the case to assess those opinions. . . . " Nowhere in the circuit court opinion does this statement appear. Rather, the court stated, "[W]e have examined the entire record *in this case*. . . . " (A 4).[3] In fact, the circuit court compared Petitioner's evidence to that "relied upon by the plaintiffs in *Turpin*". (A 3).

Also at page seven, Petitioners erroneously state as a matter of fact that

> "the Sixth Circuit panel in the instant case simply adopted the scientific conclusion pronounced by a separate Sixth Circuit panel that had reviewed a grant of summary judgment in another Bendectin case, in which the Lees were not involved and which presented a different plaintiff, different underlying facts, and the substantive law of another state."

This statement is misleading for a number of reasons. First, the Sixth Circuit Panel which ruled upon the *Turpin* appeal did not proclaim any "specific conclusions." Rather, it merely ruled[4] that

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[3] Petitioners' Appendix A is incorporated by reference herein. Unless otherwise indicated, all record cites are to Petitioners' Appendix.

[4] In so ruling, the Circuit Court clearly indicated it was not providing special treatment to Bendectin cases. "In determining and applying the correct standards of proof on summary judgment in scientific cases, we look to the rules of sufficiency of the evidence to decide whether juries should be allowed to hear the evidence as well as the rules of admissibility of expert testimony that shape the facts and opinion to be considered." (A 24).

> "[t]aken in the light most favorable to the plaintiffs, the scientific evidence that provides the foundation for the expert opinion on causation in this case is not sufficient to allow a jury to find that it is more probable than not that Bendectin caused the minor plaintiff's injury. Therefore, the case should not go to a jury.[5]

(A 19). Second, while there may have been different plaintiffs involved and different underlying facts which were not material to the issue of causation (e.g. date of birth, damages, etc.), Petitioners admitted at oral argument before the Sixth Circuit (in response to questioning by Judge Suhrheinrich) that the legal arguments were the same as in *Turpin*. While the substantive law of each state may set different thresholds of proof applicable to the party who bears that burden, Petitioners do not argue that the courts below erred in demanding proof to the level of probability.

Finally, Petitioners fail to mention that none of their experts actually reviewed the minor-plaintiffs' medical records, examined the child or concluded that Bendectin caused this specific plaintiff's birth defects. The distinct absence of any evidence to support a causal connection

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[5] For the same reason, Petitioners' statement at page eight of the Petition (that the panel in this case adopted the factual conclusions reached by the *Turpin* panel) is also incorrect. The panel below reviewed the evidence *in this case*. (A 4) ("We have examined the entire record in this case. . . . "). Moreover, this fact is implicitly recognized by Petitioners. *See*, Petition, at p.12. ("The Sixth Circuit squarely applied that approach [that the court judge for itself the validity of the reasoning process by which experts reach their conclusions, rather than the jury] in upholding summary judgment in this case.") Accordingly, Petitioners' contention that the Panel below improperly "judicially noticed" these facts is without merit.

between Bendectin and Michael Lee's birth defects is, in itself, fatal to Plaintiffs' cause of action.

1. The Pharmaceutical Product Bendectin

Merrell Dow Pharmaceuticals Inc. ("Merrell Dow") manufactured and marketed Bendectin from 1956 to 1983. Bendectin was an antinauseant, available only by prescription, for use by pregnant women to treat "morning sickness," the nausea and vomiting frequently associated with pregnancy.

As the leading treatment for morning sickness, Bendectin was prescribed in as many as 25% to 30% of all United States pregnancies. An estimated 33 million women world-wide took Bendectin during pregnancy. This broad and long term use of the product, combined with the common occurrence of birth defects in the general population, assured, merely as a matter of background incidence, that many women who had taken Bendectin would bear children with birth defects. These events spawned a monumental tort litigation.[6] Because of enormous litigation costs, Merrell Dow ceased producing Bendectin in 1983, despite the fact that it was, and still is,

[6] *Sheffield*, et al., "The Creation of Therapeutic Orphans – or What Have We Learnt From The Debendox Fiasco," 143 *Med. J. Australia* 143 (1985). In Australia and England, Bendectin was known as Debendox.

approved for marketing by the Food and Drug Administration.[7]

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2. District Court Proceedings

Plaintiffs filed this action in 1984 alleging that Mackey Lee's ingestion of Bendectin, while pregnant with her son Michael, in 1973 and 1974, caused Michael Lee to be born with a limb reduction defect consisting of shortened fingers, "webbing" and generalized smallness of his hands.[8] After extensive discovery, Merrell Dow moved in the district court for summary judgment, contending that there was no admissible evidence sufficient to raise a triable issue of fact as to whether Bendectin is capable of causing birth defects. Merrell Dow alleged that Plaintiffs could not demonstrate with admissible and sufficient evidence that a genuine issue of material fact exists whether Bendectin causes birth defects in general or, specifically, Michael Lee's birth defects. Merrell Dow supported its

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[7] In 1980, the FDA's Fertility and Maternal Health Drugs Advisory Committee, after studying the relevant literature and conducting a full hearing on the issue, concluded that "there was no increased incidence of birth defects among Bendectin-exposed infants; that there was no need for further animal or epidemiological studies; and that Bendectin should not be withdrawn from the market." The FDA adopted these findings, and to this day, continues its approval of Bendectin. *See, Richardson v. Richardson-Merrell Inc.*, 857 F.2d 823, 824, 827 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989).

[8] An agent or influence which causes physical defects in the developing embryo is called a teratogen. *Dorland's Medical Dictionary, Shorter Edition* 658 (1980).

motion with "[m]ore than thirty [epidemiological studies which] have found no causal connection between Bendectin and birth defects,"[9] (A 6), documents from the Food and Drug Administration, concluding there was no causal connection between Bendectin use and an increased incidence of birth defects,[10] and the affidavits of two experts.[11]

In response, Petitioners submitted the opinions of seven experts[12] to establish that Bendectin was a teratogen or, more succinctly, "that to a reasonable degree of certainty Bendectin is associated with limb defects." (A 3). These experts reached their opinions by considering four types of data – (1) studies of allegedly analogous chemical structures, (2) *in vitro* animal studies, (3) *in vivo*,

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[9] Merrell Dow provided summaries of thirty-five of these studies in its Exhibits in Support of Its Motion for Summary Judgment filed June 19, 1990. The accuracy of these summaries were not disputed by Plaintiffs.

[10] Because of the extensive use of Bendectin, *see, supra* p. 6, the FDA has, over the years, carefully monitored it with a particular view to its effect on the fetus. Merrell Dow offered repeated findings by the FDA that Bendectin was safe for use during pregnancy. Petitioners did not question the FDA's findings.

[11] In his affidavit, Dr. Steven H. Lamm, M.D., D.T.P.H., specifically concluded that Bendectin did not cause Michael Lee's birth defects.

[12] These opinions were contained in affidavits and testimony from prior cases. No new opinion rendered specifically for this case was relied upon by Petitioners.

or live, animal studies, and (4) reanalyses and criticisms of human epidemiological data. Petitioners erroneously argued that only their experts' opinions and not their methodologies, in assessing the value of this kind of evidence, was disputed. Accordingly, Petitioners maintained that since their experts' testimony was admissible, it, as a matter of law, was sufficient to raise a jury issue.

On January 30, 1991, after full briefing by the parties and a "thorough review of the proffered testimony", (A 3), the district court granted Merrell Dow's motion for summary judgment. (A 5). The district court measured Petitioners' expert testimony against the Sixth Circuit's test for admissibility under Federal Rules of Evidence 702 and 703.[13] Judged against these standards, the district court found that Petitioners' experts' testimony failed to meet the requirements of Rules 702 and 703 and, therefore was inadmissible:[14]

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[13] The Sixth Circuit's standard for admissibility under FRE 702 was set forth in *United States v. Green*, 548 F.2d 1261 (6th Cir. 1977) which was reaffirmed in *United States v. Kozminski*, 821 F.2d 1186 (6th Cir. 1988), *aff'd*, 487 U.S. 931 (1988), and later applied in a civil action in *Novak v. United States*, 865 F.2d 718 (6th Cir. 1989). (A 8). In determining questions of admissibility and sufficiency of the evidence, the court was deciding matters of law. (A 9).

[14] Petitioners do not here challenge the district court's holding that their experts' testimony was inadmissible, since this issue was not reached by the Court of Appeals. *See*, Petition at 6. In light of this fact, should this Court determine that *certiorari* is warranted, and upon review, reverse the Sixth Circuit, a remand thereto is necessary to allow that court to rule upon the issue of admissibility under FRE 702 and 703.

> The court finds, however, that plaintiffs' expert evidence fails to meet the test for admissibility enunciated by the Sixth Circuit in *Green* and *Kozminski* or the requirements of Rule 703, in view of the overwhelming contrary epidemiological data supporting the non-teratogenicity of Bendectin. Given the extensive human studies of Bendectin that fail to establish that Bendectin can cause birth defects, experts cannot reasonably rely on *in vivo* and *in vitro* studies that support a contrary finding. Nor can opinions based upon *in vivo* and *in vitro* studies be considered "in conformity to a generally accepted explanatory theory," in view of the overwhelming evidence from human studies.

(A 10-11).

Petitioners' experts' "relevant human data," (A 11), consisting of reanalysis of published epidemiological studies, suffered from these same shortcomings. (A 12). In fact, the conclusions based upon these reanalyses were invariably at odds with the conclusions of the studies' authors. The district court therefore, determined that Petitioners' reliance on these reanalyses was misplaced:

> [t]he remainder of this data, consisting of articles and studies, simply fails to support plaintiffs' position.
>
> * * *
>
> There is simply no epidemiological evidence supporting plaintiffs' theory of causation.

(A 12, 13).

Two additional circumstances buttressed the district court's opinion. The first was the fact that the FDA had

constantly re-examined and reaffirmed the safety of Bendectin. (A 11). Second, many other courts which considered the same issue "held that there is insufficient admissible evidence that Bendectin can cause birth defects to submit the issue to a jury." (A 13). Even more importantly, these courts considered and rejected *the same* affidavits and former trial testimony which was submitted by Petitioners in this case. (A 16).

Since Petitioners' expert evidence was determined to be inadmissible at trial, it could not be considered in deciding Respondent's motion for summary judgment. (A 17). Accordingly, the district court held that "plaintiffs [] failed to offer sufficient evidence to create a genuine issue of material fact on the causation issue," (A 17), and granted Respondent's motion.

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3. Proceedings In The Court Of Appeals

The Sixth Circuit Court of Appeals, in a *per curiam* opinion, affirmed the decision of the district court. The court examined the entire record in this case, (A 4), and found that Petitioners' experts relied upon "chemical structure analyses of doxylamine succinate, *in vitro* and *in vivo* studies and reanalyses of human epidemiological data. (A 3). The court correctly noted that

> "another panel of this Court reviewed the scientific data on Bendectin in great detail and concluded that the evidence presented by the plaintiffs' experts fell short of showing that 'Bendectin more probably than not causes limb defects in children born to mothers who

> ingested the drug at prescribed doses during pregnancy.' "

(A 3). *Citing, Turpin v. Merrell Dow Pharmaceuticals, Inc.*, No. 90-5690 (6th Cir. March 11, 1992) at 24, *petition for cert. filed*, No. 91-1987 (June 9, 1992).

Upon review of Petitioners' evidence, the court found it to be "identical in all material respects to that relied upon by the plaintiffs in *Turpin*." (A 3). In both cases, the experts as well as the bases for their opinions as to causation, "are the same." (A 3-4). For the same reasons as stated in *Turpin*, the Circuit Court held that "the plaintiffs' scientific evidence, taken as a whole, failed to create a genuine issue of material fact." (A 4). Thus, summary judgment in Respondent's favor, was appropriate. *Id.*

ARGUMENT

1. This Court Should Deny Certiorari Because This Case Does Not Involve Any Conflict Between FRCP Rule 56 and FRE Rules 704 and 705.

Under Rule 56, Federal Rules of Civil Procedure, summary judgment is proper "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which that party will have the burden of proof at trial." *Celotex Corporation v. Catrett*, 477 U.S. 317, 322 (1986). Once the moving party has demonstrated that there is no genuine issue of material fact, the non-moving party must come forward with "some significant probative evidence which

makes it necessary to resolve the parties' differing versions of the dispute at trial." *60 Ivy Street Corporation v. Alexander*, 852 F.2d 1432, 1435 (6th Cir. 1987); *see also Matsushita Electric Industrial Co., Ltd. v. Zenith Radio, Corp.*, 475 U.S. 574, 586-587 (1986); *Potters Medical Center v. City Hospital Association*, 800 F.2d 568, 572 (6th Cir. 1986).

The central question posed by any summary judgment motion is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-252 (1986). This standard asks, not whether *any* jury could find for the non-moving party, but rather whether there is "evidence on which the jury could *reasonably*" find for the non-moving party. *Id.* (emphasis added). This review by the trial court should not focus on individual pieces of evidence or isolated facts. Rather, the court is directed to grant summary judgment "[w]here the record taken as a *whole* could not lead a *rational* trier of fact to find for the non-moving party. . . . " *Matsushita*, 475 U.S. at 587 (emphasis added).

Rule 56 provides that a summary judgment is proper if the non-moving party is unable to come forward with sufficient evidence to enable a reasonable jury to find in favor of the non-movant on a material issue of fact. Rule 56(e) requires that, in order to defeat a well supported summary judgment motion, the non-movant must counter the motion with evidence sufficient to raise a genuine issue of material fact. The non-moving party may oppose a motion for summary judgment with expert testimony in the form admissible under Rules 704 and 705. However, if evidence, expert or otherwise, fails to set forth specific

facts *sufficient* to raise a genuine issue of material fact, it will not defeat a well pled motion for summary judgment.

In contrast to Rule 56, Rules 704 and 705, Federal Rules of Evidence, address only the admissibility of expert testimony, not the sufficiency of any such evidence to support a party's case on any particular fact. Rule 704(a) permits testimony, otherwise admissible, to "embrace an ultimate fact," and Rule 705 provides that an expert's opinion and reasons for that opinion are *admissible* without prior disclosure of the underlying basis of that opinion. Rule 705 also prescribes that an expert may be required by the court to disclose the basis of any opinion admitted under Rule 705. The Federal Rules of Evidence do not attempt to define a jury case or state categorically what kind of evidence a reasonable jury may accept. Petitioners' argument that there is a conflict between Rule 56 and Rules 704 and 705 ignores this inherent distinction between admissibility and sufficiency of evidence and seeks to replace the sufficiency standard enunciated by this Court with a "mere presence of evidence" standard.

In this case, the Sixth Circuit did not address the district court's holding which excluded Petitioners' evidence as inadmissible under the Rules of Evidence. (A 4). The Sixth Circuit bypassed the issue of admissibility and judged the evidence against the summary judgment standard and held that "the plaintiffs' scientific evidence, taken as a whole, fails to create a genuine issue of material fact." (A 4). The Circuit Court determined that Petitioners failed to present sufficient evidence to allow a reasonable jury to find in their favor: "a finding of a

causal relationship between Bendectin use and Michael Lee's birth defects based upon this evidence would be conjectural at best." (A 3). In the absence of this threshold level of evidence, summary judgment was proper. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986).

Contending that there is conflict among the circuits over the interaction of Rule 56 and Rules 704 and 705, Petitioners cite to several cases, none of which supports their contention. For example, in *Quinton v. Farmland Industries, Inc.*, 928 F.2d 335 (10th Cir. 1991), the court, on a motion for judgement notwithstanding the verdict, reviewed the basis of the expert's opinion to determine whether the opinion could support the jury verdict in favor of the plaintiff. The Tenth Circuit held that the particular expert testimony admitted there was sufficient to support the jury verdict and denied the motion. *Id.*, at 338. The Tenth Circuit did not hold, as Petitioners imply, that any expert testimony, *however implausible*, precludes any challenge to the sufficiency of evidence on a factual issue. Petition at 15. Petitioners reliance on the cases of *United States v. A&S Council Oil Co.*, 947 F.2d 1128 (4th Cir. 1991) and *Smith v. Ford Motor Co.*, 626 F.2d 784 (10th Cir. 1980), *cert. denied*, 454 U.S. 918 (1981) is likewise misplaced, as these cases deal with the scope of pretrial discovery of an expert's opinions, their bases and the scope of cross examination at trial.

Petitioners' citation to opinions of the D.C. Circuit,[15] specifically, *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529

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[15] In *U.S. v. Wright*, 783 F.2d 1091 (D.C. Cir. 1986) which predates *Richardson*, the Court addressed the exception under

(D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), is puzzling. That same court in *Richardson v. Richardson-Merrell Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989), granted judgment notwithstanding the verdict for Respondent, and there distinguished *Ferebee* as being limited to cases involving the "frontiers" of science and not those cases where, as here, a settled scientific consensus has been reached. *Id.* at 831-832.

Ambrosini v. Labarraque, Nos. 90-7146, 7148 *slip op.* (D.C. Cir. June 12, 1992), is equally unhelpful to Petitioners. First, the D.C. Circuit stated, contrary to Petitioners' position here, that "[t]his Court, as well as others, has recognized that the issue of admissibility of an expert's opinion under Rules 703 and 705 is *separate* and *distinct* from the issue whether the testimony is sufficient to withstand a motion for summary judgment under Rule 56." (citations omitted, emphasis added). (A 50). Second, the record at the summary judgment stage in *Ambrosini* differed much from the record as it exists in this case.

In *Ambrosini*, plaintiffs opposed summary judgment with affidavits containing only "bare conclusions[s]" about causation.[16] In the words of the D.C. Circuit:

FRE 703 which allows the admissibility of the basis of an expert's opinion even if that basis is in the form of otherwise inadmissible hearsay. *Id.*, at 1100-1101. The Court did not address the issue of the sufficiency of such opinion testimony under FRCP 56.

[16] "Dr. Goldman's affidavit did not, however, explain in detail the basis for his conclusion nor did it specifically state which studies, reports, or articles he relied on.

* * *

> "At that point, pursuant to Rule 705, the Court could have required [the affiants] to disclose the bases for their opinions so that it could determine whether the opinions had an adequate foundation. . . . Only then could the court determine whether the affidavits were admissible. . . .

(A 48).

> . . . even if the expert affidavits were admissible . . . , summary judgment would have been proper if the affidavits were not sufficient to create a genuine issue of material fact.

(A 50). In the case at bar however, the record is far from bare. It contains affidavits and actual testimony from other cases clearly delineating the bases upon which Petitioners' experts relied. Here the court could judge whether the expert's conclusions plausibly followed from their data. The court found that they did not. Thus, *Ambrosini* is inapposite.

Petitioners' reading of *DeLuca v. Merrell Dow Pharmaceutical*, 911 F.2d 941 (3rd Cir. 1990) is simply incorrect. In *DeLuca*, the Third Circuit held that there was insufficient evidence in the record to support the district court's exclusion of plaintiff's expert testimony under FRE 703. *Id.* at 953. The Third Circuit, did *not*, as Petitioners suggest, hold that summary judgment was never proper when there is admissible expert testimony. In fact, the Third Circuit expressly acknowledged the possibility that, on remand, the district court could grant summary

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Dr. Strom's affidavit also did not identify the publications, studies, or methodology he used in forming his opinion." (A 42).

judgment for Merrell Dow if it found the *admissible expert testimony insufficient to raise a jury issue*. The Court stated:

> . . . [E]ven if Dr. Done's epidemiological analysis is found to be admissible, the DeLucas are entitled to get to trial only if the district court is satisfied that this analysis together with any other evidence relevant to the causation issue would permit a jury finding that [plaintiff's] birth defects were, when measured against the appropriate burden of proof, caused by her mother's exposure to Bendectin. *Id.* at 959.

Despite Petitioners' neglect of the distinction between admissibility of evidence and sufficiency of evidence, there exists no inherent or court created conflict between Rule 56 of the Federal Rules of Civil Procedure and Rules 704 and 705 of the Federal Rules of Evidence. The only conflict present in this case is the one between Petitioners' lack of evidence and the required burden of proof. Lacking *sufficient* evidence to meet this burden, Petitioners ask this Court to change the burden of proof to meet the evidence.

2. This Court Should Deny Certiorari Because The Sixth Circuit Correctly Applied The Standard For Summary Judgment Established By This Court.

Petitioners do not, nor can they, contend that the court below erred in relying on the summary judgment standard established by this Court in *Celotex Corporation v. Catrett*, 477 U.S. 317 (1986) and *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986). In those cases, this Court explicitly rejected the argument that the presence of any evidence, no matter how minimal, was sufficient to defeat a well pled motion for summary judgment. Rather, the

lower courts were directed to answer the central question "whether the evidence presents a *sufficient disagreement* to require submission to a jury or whether it is so *one-sided* that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-252 (1986) (emphasis added). In rejecting the "scintilla" standard, this Court restored summary judgment as a viable judicial tool for the early resolution of cases where one party could not present sufficient evidence to allow a reasonable jury to find in its favor.

The fact that, in 1985, (well before the decision below), a "common issues" trial was permitted to go to a jury is of no moment. Plaintiffs' experts evidence in that case was not challenged by a motion for summary judgment before trial. *In re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F. Supp. 1212 (S.D. Ohio 1985), *aff'd, sub nom, In re Bendectin Litigation. Hoffman v. Merrell Dow Pharmaceuticals, Inc.*, 857 F.2d 290 (6th Cir. 1988), *cert. denied*, 488 U.S. 1066 (1989). Finally, and as recognized by the D.C. Circuit in *Ambrosini* (upon which Petitioners' rely), "[s]cience is a rapidly changing field- . . . Our decisions must leave the way open for these changes." (A 49). An overwhelming consensus of the relevant scientific community has been reached – Bendectin does not cause birth defects. This consensus, obviously recognized and accepted by the jury in the common issues trial, has grown even stronger. In fact, this medicine has been called the best studied human non-teratogen. "Bendectin, Our Most Famous Tortogen-Litogen And The Best Studied Human Non-teratogen," 37 *Teratology* 447 (1988). Petitioners argue that, even though they opted-out of the Bendectin "common issues" trial, they are being held to the defense verdict rendered there and affirmed

by the Sixth Circuit. That a long litigation generates legal precedents which thereafter guide the courts in disposing of the individual cases does not effectuate a "pseudo-class action." As noted above, the lower courts reviewed the evidence presented in *this* case. Although the scientific consensus and evidence as to the safety of Bendectin continues to grow, Petitioners relied upon the same evidence that has been rejected by the FDA, by an ever growing list of judicial decisions and by the relevant scientific community. That a trend in results[17] is observable is due, not to manipulation by the judiciary, but by the predictable body of evidence which is being repeatedly presented.

Here, the Sixth Circuit correctly applied the summary judgment standard and after a full review of an extensive and detailed record, affirmed summary judgment for the Respondent. The Court of Appeals found that, although Petitioners had presented some evidence to support their claim, that evidence "could not lead a rational trier of fact to find for the [petitioners]." *Matsushita*, 475 U.S. at 587.

This case presents no intercircuit conflict over the proper summary judgment standard. This case presents only Petitioners' dissatisfaction with the adverse outcome

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[17] Petitioners argument that the decisions below breed inconsistency rests upon a complete mischaracterization of the decision of the Michigan Court of Appeals in *DePyper v. Navarro*, No. 116380, *slip op.* (Mich. App. May 9, 1991). The Michigan Court of Appeals did not address the sufficiency of the plaintiffs' evidence. It merely held the trial court's ruling that plaintiffs' evidence was inadmissible premature because, in its view, a *Davis/Frye* ruling, mandated by Michigan law, was not conducted. (A 56).

resulting from the Circuit Court's conventional and considered application of this Court's summary judgment standard. The Circuit Court did not, as Petitioners suggest, base its decision on an expanded concept of judicial notice or a casual adoption of the factual opinions of other courts which have ruled on summary judgment motions in other Bendectin cases. To the contrary, the Circuit Court reviewed the evidence presented in this case and rejected it as insufficient to require its submission to a jury. Since this evidence was "identical in all material respects to the evidence," previously reviewed and rejected by another panel in *Turpin*, the court correctly applied its own precedent decision. This case involves no abuse of judicial power, no attack on the *Erie* doctrine, no imposition of some national tort law, and no creation of an *ad hoc* procedural device. It involves nothing more than the review of the evidence under the summary judgment standard consistently articulated by this Court. The Sixth Circuit did not engage in unbridled judicial activism. To the contrary, the Sixth Circuit engaged in the exercise of judicial responsibility.

Petitioners ask nothing less than that this Court rewrite the Federal Rules of Evidence and the Federal Rules of Civil Procedure to carve out a unique place in the law for expert testimony. They would have this Court rule that, for expert testimony, there is no test for sufficiency but only blind and uncritical acceptance. Under such a new rule, summary judgment would be precluded *whenever* an expert is willing to testify to some factual position. Under Petitioners' theory of the law, courts would be compelled to accept an expert's opinion that the

moon is made of cheese and further find that opinion sufficient to justify submission of the issue to a jury.

CONCLUSION

This Court should deny certiorari because Petitioners have failed to raise any issue for review which would have application beyond the confines of this solitary case. There has been no untoward exercise of judicial activism by the Circuit Court. There has been no imposition of some universal federal Bendectin law. No erosion has occurred of the boundaries drawn by the *Erie* doctrine.

What the Sixth Circuit has done, and what Petitioners wish this Court to undo, is apply this Court's well settled principles of summary judgment to the *unique* facts of this one case and find those facts insufficient to allow a reasonable jury to find in favor of Petitioners. Petitioners oppose that finding and ask this Court to again review the factual record and again make a finding of facts – a task the lower courts have twice done before.

Petitioners' claims of inherent conflict between Rule 56 of the Federal Rules of Civil Procedure and Rules 704 and 705 of the Federal Rules of Evidence lack any basis in fact or law. In the absence of any issues of law that reach beyond this case, there is no policy for this Court to address and no purpose for review. Any decision rendered in this case would reach no further than these litigants.

For all of the aforementioned reasons, this Court should deny *certiorari*.

Respectfully submitted,

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